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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

IN RE: BEXTRA AND CELEBREX
MARKETING SALES PRACTICES AND
PRODUCT LIABILITY LITIGATION

MDL No. 1699

Johnnie L. West, individually

Plaintiff,

v.

PFIZER, INC., PHARMACIA
CORPORATION, G.D. SEARLE LLC, (FKA
G.D. SEARLE & CO.), and MONSANTO
COMPANY,

Defendants.

CV 07

5687

CIVIL COMPLAINT

JURY TRIAL DEMANDED

Johnnie West ("Plaintiff"), by and through her undersigned counsel, brings this
action for damages against Defendants PFIZER, INC., PHARMACIA CORPORATION, G.D.
SEARLE LLC, (FKA G.D. SEARLE & CO.) and MONSANTO COMPANY (hereafter
"Defendants") for damages arising from Defendants' design, manufacture, sale, testing,

1 marketing, advertising, promotion, and/or distribution of the unsafe medication Valdecoxib, trade
2 name BEXTRA® (“BEXTRA”).

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4 **I. PARTIES**

5 1. Plaintiff is, and was at all relevant times, an adult resident citizen of Wayne
6 County, Michigan.

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8 2. Defendant PFIZER INC. (“PFIZER”) is a Delaware corporation with its
9 principal place of business in New York, New York. In 2003, PFIZER acquired Pharmacia
10 Corporation for nearly \$60 billion. At all relevant times PFIZER and/or its predecessors in
11 interest were engaged in the business of designing, testing, manufacturing, packaging, marketing,
12 distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA
13 nationwide.

14 3. Defendant G. D. SEARLE LLC, formerly known as G. D. Searle & Co.
15 (“SEARLE”) is a Delaware corporation with its principal place of business in Illinois. At all
16 relevant times, Searle has been engaged in the business of marketing and selling BEXTRA
17 nationwide. Searle is a subsidiary of PFIZER, acting as its agent and alter ego in all matters
18 alleged within this Complaint.

19
20 4. Defendant PHARMACIA CORPORATION (“PHARMACIA”) is a
21 Delaware corporation with its principal place of business in New Jersey. At all relevant times,
22 PHARMACIA, and its predecessors in interest have been engaged in the business of designing,
23 testing, manufacturing, packaging, marketing, distributing, promoting, and selling BEXTRA
24 nationwide.

25 5. Defendant MONSANTO COMPANY (“MONSANTO”) was the parent
26 corporation of SEARLE and is a Delaware corporation. At all times relevant hereto,
27 MONSANTO, through its subsidiary companies, was in the business of manufacturing,
28 marketing, selling and distributing the pharmaceutical product BEXTRA nationwide.

1 6. At all times relevant to this action, Defendants intentionally, recklessly
2 and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects,
3 and disadvantages of BEXTRA, and advertised, promoted, marketed, sold and distributed
4 BEXTRA as a safe prescription medication when, in fact, Defendants had reason to know, and
5 did know, that BEXTRA was not safe for its intended purposes, for the patients for whom it was
6 prescribed, and for whom it was sold; and that BEXTRA caused serious medical problems, and in
7 certain patients, catastrophic injuries and deaths.

8 7. In engaging in the conduct alleged herein, each Defendant acted as the
9 agent for each of the other Defendants, or those Defendant's predecessors in interest.

10 **II. JURISDICTION AND VENUE**

11 8. This Court has subject matter jurisdiction over this matter pursuant to
12 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds \$75,000.00 and
13 there is complete diversity of citizenship between Plaintiff and Defendants.

14 9. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391.
15 Defendants marketed, advertised and distributed the dangerous product in this district, thereby
16 receiving substantial financial benefit and profits from sales of the dangerous product in this
17 district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

18 10. At all relevant times herein, Defendants were in the business of designing,
19 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and
20 selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed,
21 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce
22 the aforementioned prescription drug. Defendants do substantial business Nationwide and within
23 this District, advertise in this district, receive substantial compensation and profits from sales of
24 CELEBREX in this District, and made material omissions and misrepresentations and breaches of
25 warranties in this District so as to subject them to *in personam* jurisdiction in this District. In
26 engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other
27 Defendants or those Defendant's predecessors in interest.
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1 **III. INTERDISTRICT ASSIGNMENT**

2 11. Assignment to the Northern District of California, San Francisco Division,
3 is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is
4 related to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699,
5 assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on
6 September 6, 2005.

7 **IV. FACTUAL BACKGROUND**

8 **A. Facts Regarding Plaintiff**

9 12. Plaintiff was prescribed and began taking BEXTRA for the treatment of
10 pain on or about November, 2003,.

11 13. As a direct and proximate result of using BEXTRA, on or about
12 November, 4, 2004, Plaintiff suffered a serious cardiovascular injury or heart attack.

13 14. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's
14 injuries unaware—and could not have reasonably known or have learned through reasonable
15 diligence—that such injury directly resulted from Plaintiff's ingestion of BEXTRA and
16 Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations.

17 15. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and
18 used it in a condition that was substantially the same as the condition in which it was
19 manufactured and sold.

20 16. Plaintiff would not have purchased and used BEXTRA had Defendants
21 properly disclosed the risks associated with the drug, and through diligent effort was not able to
22 discover the risk from BEXTRA prior to use of the drug.

23 **B. Facts Regarding Bextra's Market Launch**

24 17. BEXTRA is one of a class of pain medications called non-steroidal anti-
25 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade
26 name Advil) are examples of well-known NSAIDs.

27 18. NSAIDs reduce pain by blocking the body's production of pain
28 transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX

1 enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and
2 COX-2 enzymes.

3 19. In addition to decreasing inflammation, the prostaglandins that are
4 supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the
5 stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the
6 medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric
7 tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including
8 stomach ulceration and bleeding.

9 20. Prostaglandin I₂ is the predominant cyclooxygenase product in
10 endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation,
11 and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit
12 Thromboxane A₂ and Prostaglandin I₂, the COX-2 inhibitors leave Thromboxane A₂ unaffected.
13 Thromboxane A₂ is a potent platelet aggregator and vasoconstrictor, which is synthesized by
14 platelets. Therefore, while the older NSAIDS suppress platelet aggregation and vasoconstriction,
15 the COX-2 inhibitors support it.

16 21. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore
17 pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected,
18 traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause
19 blood clots, rather they actually reduce the risk of clots and help protect heart function.

20 22. Defendants and other pharmaceutical companies set out to remedy these
21 ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors
22 that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of
23 gastric tissue while still reducing inflammation.

24 23. In making this decision, Defendants and their predecessors in interest either
25 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
26 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
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1 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke
2 and unstable angina.

3 24. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor
4 drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and
5 consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In
6 May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

7 25. Seeking increased market share in this extremely lucrative market,
8 Defendants, and their predecessors in interest, also sought approval of a “second generation”
9 selective COX-2 inhibitor and filed for FDA approval of BEXTRA on January 16, 2001 for the
10 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief
11 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

12 26. The FDA granted approval of the new drug on November 16, 2001, for two
13 particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms
14 of osteoarthritis and rheumatoid arthritis.

15 27. The FDA did not grant approval to market and promote BEXTRA for the
16 management or prevention of acute pain.

17 28. The FDA did not grant approval to promote BEXTRA as more effective
18 than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations,
19 ulcers or gastric bleeding.

20 29. Even without a label that allowed Defendants to legitimately claim superior
21 safety, when Defendants, and their predecessors-in-interest, began marketing BEXTRA in early
22 2002, Defendants and their representatives and agents misrepresented the safety profile of
23 BEXTRA to consumers, including Plaintiff, the medical community, healthcare providers, and
24 third party payers. Defendants proceeded to promote, market, sell, and distribute BEXTRA as a
25 much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and
26 ibuprofen.

1 **C. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.**

2 30. The potential for cardiovascular risk of selective COX-2 inhibitors was
3 known to Defendants long before the FDA granted market approval in November 2, 2001. By
4 1997, and prior to the submission of the New Drug Application (the "NDA") for BEXTRA,
5 Defendants was aware that, by inhibiting COX-2, BEXTRA altered the homeostatic balance
6 between prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects
7 of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of*
8 *Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at
9 954. Although all COX-2 inhibitors have this mechanism of action, BEXTRA was the most
10 selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to
11 cause adverse cardiovascular and cerebrovascular events.

12 31. Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania,
13 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,
14 that it was known as early as 1999 that selective COX-2 inhibitors, such as BEXTRA, suppressed
15 the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro,
16 and may predispose patients to myocardial infarction or thrombotic stroke.

17 32. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the
18 FDA for BEXTRA, omitting information about the extent of the risks associated with BEXTRA.
19 Without a complete picture of the potential hazards associated with the drug, the FDA approved
20 BEXTRA on or about November 16, 2001.

21 33. Based on the studies performed on Celebrex, Vioxx, BEXTRA, and other
22 COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely
23 conducted, Defendants knew when BEXTRA was being developed and tested that selective
24 COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a
25 specific additional threat to anyone with existing heart disease or cardiovascular risk factors.
26 Studies show that selective COX-2 inhibitors, including BEXTRA, decrease blood levels of a
27 prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood
28 pressure, heart attack, and stroke.

1 34. On December 9, 2004, the FDA issued new information on side effects
2 associated with the use of BEXTRA and required the addition of certain warnings to, and the
3 strengthening of other warnings on, the BEXTRA label. The enhanced warnings followed in the
4 wake of the results of additional cardiovascular studies performed by Defendants, as well as
5 numerous complaints to the FDA regarding severe skin reactions.

6 35. Yet well prior to this warning, Defendants had knowledge of the coronary
7 and cardiovascular safety risks of BEXTRA from several studies. *See e.g., Otto, E.O., Efficacy*
8 *and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing*
9 *Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June
10 2003 at 1481.

11 36. Even Defendants' own (and Pfizer funded) post- drug approval meta-
12 analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data
13 showing an increased cardiovascular risk in patients treated with BEXTRA after undergoing
14 coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood
15 clots in the legs and lungs. The results were particularly relevant and striking as each of the study
16 participants who were a post-bypass surgery patient was taking anti-clotting agents at the time
17 their exposure to BEXTRA was being tracked.

18 37. In mid-January 2005, a peer-reviewed paper from the University of
19 Pennsylvania found that in patients having heart bypass surgery, those who took BEXTRA in the
20 intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a
21 heart attack or stroke.

22 38. From February 16-18, 2005, the FDA's Drug Safety and Risk Management
23 Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine
24 the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham
25 testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at
26 about the same rate as cigarette smoking, hypertension, and diabetes.

1 39. Despite years of studies on selective COX-2 inhibitors, as well as the
2 disturbing new studies specifically analyzing the risks of BEXTRA, Defendants failed to take any
3 action to protect the health and welfare of patients, but instead, continued to promote the drug for
4 sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis
5 Drug Advisory Committee meetings.

6 40. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily
7 withdraw" BEXTRA from the U.S. market, stating:

8
9 "... the Agency has concluded that the overall risk versus benefit
10 profile of BEXTRA is unfavorable. This conclusion is based on the
11 potential increased risk for serious cardiovascular (CV) adverse
12 events, which appears to be a class effect of non-steroidal anti-
13 inflammatory drugs (NSAIDs) (excluding aspirin), an increased
14 risk of serious skin reactions (e.g. toxic epidermal necrolysis,
15 Stevens-Johnson syndrome, erythema multiforme) compared to
16 other NSAIDs, and the fact that BEXTRA has not been shown to
17 offer any unique advantage over the other available NSAIDs."

18 FDA Alert for Healthcare Professionals, April 7, 2005.

19 41. Continuing, the FDA noted:

20 "BEXTRA has been demonstrated to be associated with an
21 increased risk of serious adverse CV events in two short-term trials
22 in patients immediately post-operative from coronary artery bypass
23 graft (CABG) surgery FDA has concluded that it is reasonable
24 to extrapolate the adverse CV risk information for BEXTRA from
25 the short-term CABG trials to chronic use given the fact that other
26 COX-2 selective NSAIDs have been shown in long-term controlled
27 clinical trials to be associated with an increased risk of serious
28 adverse CV events (e.g., death, MI, stroke), and the well described
 risk of serious, and often life-threatening gastrointestinal
 bleeding To date, there have been no studies that demonstrate
 an advantage of BEXTRA over other NSAIDs that might offset the
 concern about the [] serious skin risks, such as studies that show a
 GI safety benefit, better efficacy compared to other products, or
 efficacy in a setting of patients who are refractory to treatment with
 other products."

1 42. The scientific data available during and after BEXTRA's approval process
2 made clear to Defendants that their formulation of BEXTRA would cause a higher risk of blood
3 clots, stroke and/or myocardial infarctions among BEXTRA consumers, alerting them to the need
4 to do additional and adequate safety studies.

5 43. As stated by Dr. Topol on October 21, 2004, in *The New England Journal*
6 *of Medicine*, outlining Defendants' failure to have conducted the necessary trials before
7 marketing to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular
8 risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with
9 established coronary artery disease, who frequently have coexisting osteoarthritis requiring
10 medication and have the highest risk of further cardiovascular events."

11 44. Dr. Topol was also the author on the study published in August 2001 in
12 JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in
13 persons who used COX-2 inhibitors.

14 45. Based upon readily available scientific data, Defendants knew, or should
15 have known, that their pre-approval testing of BEXTRA did not adequately represent the cross-
16 section of individuals who were intended consumers and therefore, likely to take BEXTRA.
17 Therefore, Defendants' testing and studies were grossly inadequate. *See, e.g.*, PDR entry for
18 BEXTRA.

19 46. Had Defendants done adequate testing prior to approval and "market
20 launch," rather than the extremely short duration studies done on the small size patient base that
21 was actually done, Pharmacia and Searle's scientific data would have revealed significant
22 increases in incidence of strokes and myocardial infarctions among the intended and targeted
23 population of BEXTRA consumers. Adequate testing would have shown that BEXTRA
24 possessed serious side effects for individuals such as Plaintiff. Defendants should have taken
25 appropriate measures to ensure that their defectively designed product would not be placed in the
26 stream of commerce and/or should have provided full and proper warnings accurately and fully
27 reflecting the scope and severity of symptoms of those side effects should have been made.
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1 47. In fact, post-market approval data did reveal increased risks of clotting,
2 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants
3 in order for them to gain significant profits from continued BEXTRA sales.

4 48. Defendants' failure to conduct adequate testing and/or additional testing
5 prior to "market launch" was based upon their desire to generate maximum financial gains for
6 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
7 inhibitor market.

8 49. At the time Defendants manufactured, advertised, and distributed
9 BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld
10 information regarding the increased risks of hypertension, stroke and/or myocardial infarctions
11 because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiff
12 would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAIDs.

13 **D. Facts Regarding Defendants' Marketing and Sale of Bextra**

14 50. At all times relevant herein, Defendants engaged in a marketing campaign
15 with the intent that consumers would perceive BEXTRA as a safer and better drug than its other
16 NSAIDs and, therefore, purchase BEXTRA.

17 51. Defendants widely and successfully marketed BEXTRA throughout the
18 United States by, among other things, conducting promotional campaigns that misrepresented the
19 efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was
20 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.
21 Defendants made misrepresentations by means of media advertisements, and statements
22 contained in sales literature provided to Plaintiff's prescribing physicians.

23 52. Despite knowledge of the dangers presented by BEXTRA, Defendants and
24 Defendants' predecessors in interest, through their officers, directors and managing agents for the
25 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy
26 the known defects of Defendants' product, BEXTRA, and failed to warn the public, including
27 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,
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1 BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the
2 inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product,
3 BEXTRA, knowing that persons would be exposed to serious potential danger, in order to
4 advance their own pecuniary interests. Defendants' conduct was wanton and willful, and
5 displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

6 53. In an elaborate and sophisticated manner, Defendants aggressively
7 marketed BEXTRA directly to consumers and medical professionals (including physicians and
8 leading medical scholars) in order to leverage pressure on third party payers, medical care
9 organizations, and large institutional buyers (*e.g.*, hospitals) to include BEXTRA on their
10 formularies. Faced with the increased demand for the drug by consumers and health care
11 professionals that resulted from Defendants' successful advertising and marketing blitz, third
12 party payers were compelled to add BEXTRA to their formularies. Defendants' marketing
13 campaign specifically targeted third party payers, physicians, and consumers, and was designed to
14 convince them of both the therapeutic and economic value of BEXTRA.

15 54. Defendants represented that BEXTRA was similar to ibuprofen and
16 naproxen but was superior because it lacked any of the common gastrointestinal adverse side
17 effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For
18 instance, NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding
19 with long-term use. Defendants promoted BEXTRA as a safe and effective alternative that would
20 not have the same deleterious and painful impact on the gut, but that would be just as effective, if
21 not more so, for pain relief.

22 55. BEXTRA possessed dangerous and concealed or undisclosed side effects,
23 including the increased risk of serious cardiovascular events, such as heart attacks, unstable
24 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as
25 strokes. In addition, BEXTRA was no more effective than traditional and less expensive NSAIDS
26 and, just like traditional NSAIDS, carried a risk of perforations, ulcers, and gastrointestinal
27 bleeding. Defendants chose not to warn about these risks and dangers.

1 56. Defendants knew of these risks before the U.S. Food and Drug
2 Administration (the "FDA") approved BEXTRA for sale on November 16, 2001, but Defendants
3 ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied
4 inefficacy in its promotion, advertising, marketing, and sale of BEXTRA. Defendants' omission,
5 suppression, and concealment of this important information enabled BEXTRA to be sold to, and
6 purchased, or paid for by, the Consumers at a grossly inflated price.

7 57. Consequently, BEXTRA captured a large market share of anti-
8 inflammatory drugs prescribed for and used by patients. In 2002 alone (after a drug launch in
9 March of 2002), sales of BEXTRA exceeded \$1.5 billion, despite the significantly higher cost of
10 BEXTRA as compared to other pain relievers in the same family of drugs.

11 58. It was not until April 7, 2005, that Defendants finally acknowledged
12 BEXTRA's deleterious side effects and announced that they were withdrawing the drug from the
13 worldwide market based on what it misleadingly termed "new" and "unexpected" evidence
14 linking BEXTRA to an increased risk of heart attacks and strokes.

15 59. Had Defendants done adequate testing prior to approval and "market
16 launch," Pharmacia's scientific data would have revealed significant increases in stroke and
17 myocardial infarction amongst the intended population of BEXTRA consumers. Adequate
18 testing would have shown that BEXTRA possessed serious side effects. Defendants should have
19 taken appropriate measures to ensure that their defectively designed product would not be placed
20 in the stream of commerce and/or should have provided full and proper warnings accurately and
21 fully reflecting the scope and severity of symptoms of those side effects should have been made.

22 60. In fact, post-market approval data did reveal increased risks of clotting,
23 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants
24 in order for them to gain significant profits from continued BEXTRA sales.

25 61. Defendants' failure to conduct adequate testing and/or additional testing
26 prior to "market launch" was based upon their desire to generate maximum financial gains for
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1 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
2 inhibitor market.

3 62. At the time Defendants manufactured, advertising, and distributed
4 BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld
5 information regarding the increased risks of hypertension, stroke and/or myocardial infarctions
6 because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff
7 would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

8 63. At all times relevant herein, Defendants engaged in a marketing campaign
9 with the intent that consumers, including plaintiff, and their doctors would perceive BEXTRA as
10 a better drug than its competitors and, therefore, purchase BEXTRA.

11 64. Defendants widely and successfully marketed BEXTRA throughout the
12 United States by, among other things, conducting promotional campaigns that misrepresented the
13 efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was
14 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.
15 Defendants made misrepresentations by means of media advertisements, and statements
16 contained in sales literature provided to Plaintiff's prescribing physicians.

17 65. Prior to manufacturing, sale and distribution of BEXTRA, Defendants,
18 through their officers, director and managing agents, had notice and knowledge from several
19 sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As
20 such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or
21 death from the consumption of Defendants' product, BEXTRA.

22 66. Despite such knowledge, Defendants and Defendants' predecessors in
23 interest, through their officers, directors and managing agents for the purpose of increasing sales
24 and enhancing its profits, knowingly and deliberately failed to remedy the known defects of
25 Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious
26 risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants
27 and their officers, agents and managers intentionally proceeded with the inadequate testing, and
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1 then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that
2 persons would be exposed to serious potential danger, in order to advance their own pecuniary
3 interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for
4 the safety of the public and particularly of Plaintiff.

5 **CLAIMS FOR RELIEF**

6 **FIRST CLAIM FOR RELIEF**

7 **Negligence**

8 67. Plaintiff incorporates by reference all of the paragraphs of this Complaint
9 as if fully set forth herein.

10 68. Defendants owed Plaintiff a duty to exercise reasonable care when
11 designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty
12 included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of
13 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side
14 effects.

15 69. At all relevant times to this action, Defendants owed a duty to properly
16 warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical
17 drug BEXTRA.

18 70. Defendants breached their duties by failing to exercise ordinary care in the
19 preparation, design, research, testing, development, manufacturing, inspection, labeling,
20 marketing, promotion, advertising and selling of BEXTRA, including:

21 (a) failing to use due care in the preparation and development of
22 BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were
23 ingested;

24 (b) failing to use due care in the design of BEXTRA to prevent the
25 aforementioned risk of injuries to individuals when the drugs were ingested;

26 (c) failing to conduct adequate pre-clinical testing and research to
27 determine the safety of BEXTRA;
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1 (d) failing to conduct adequate post-marketing surveillance and
2 exposure studies to determine the safety of BEXTRA;

3 (e) failing to completely, accurately and in a timely fashion, disclose
4 the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff,
5 consumers, the medical community, and the FDA;

6 (f) failing to accompany BEXTRA with proper warnings regarding all
7 possible adverse side effects associated with the use of BEXTRA;

8 (g) failing to use due care in the manufacture, inspection, and labeling
9 of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;

10 (h) failing to use due care in the promotion of BEXTRA to prevent the
11 aforementioned risk of injuries to individuals when the drugs were ingested;

12 (i) failing to use due care in the sale and marketing of BEXTRA to
13 prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

14 (j) failing to use due care in the selling of BEXTRA to prevent the
15 aforementioned risk of injuries to individuals when the drugs were ingested;

16 (k) failing to provide adequate and accurate training and information to
17 the sales representatives who sold BEXTRA;

18 (l) failing to provide adequate and accurate training and information to
19 healthcare providers for the appropriate use of BEXTRA; and

20 (m) being otherwise reckless, careless and/or negligent.

21 71. Despite the fact that Defendants knew or should have known that
22 BEXTRA caused unreasonable and dangerous side effects which many users would be unable to
23 remedy by any means, Defendants continued to promote and market BEXTRA to consumers,
24 including Plaintiff, when safer and more effective methods of pain relief were available.

25 72. Defendants were, or should have been had they exercised reasonable care,
26 in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless,
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1 they continued to market their products by providing false and misleading information with
2 regard to the safety and efficacy of BEXTRA.

3 73. Defendants knew or should have known that consumers such as Plaintiff
4 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described
5 above.

6 74. As a direct and proximate consequence of Defendants' acts, omissions, and
7 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has
8 required and will require healthcare and services; has incurred and will continue to incur medical
9 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
10 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
11 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
12 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
13 direct medical losses and costs include care for hospitalization, physician care, monitoring,
14 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

15 75. Defendants' conduct was committed with knowing, conscious, wanton,
16 willful, and deliberate disregard for the value of human life and the rights and safety of
17 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
18 as to punish Defendants and deter them from similar conduct in the future.

19 76. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
20 compensatory damages, and exemplary and punitive damages together with interest, the costs of
21 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

22 **SECOND CLAIM FOR RELIEF**
23 **Strict Liability**

24 77. Plaintiff incorporates by reference all previous paragraphs of this
25 Complaint as if fully set forth herein and further alleged as follows:

26 78. At all times relevant to this action, Defendants were suppliers of BEXTRA,
27 placing the drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiff
28 without substantial change in the condition in which it was manufactured and sold.

1 79. BEXTRA was unsafe for normal or reasonably anticipated use.

2 80. BEXTRA was defective in design or formulation because when it left the
3 hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous
4 than an ordinary consumer would expect. BEXTRA was also defective and unreasonably
5 dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated
6 with the design and/or formulation of the product.

7 81. BEXTRA is unreasonably dangerous: (a) in construction or composition;
8 (b) in design; (c) because an adequate warning about the product was not provided; (d) because it
9 does not conform to an express warranty of the manufacturer about the product .

10 82. BEXTRA as manufactured and supplied by Defendants was also defective
11 due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate
12 reporting regarding the results of the clinical trials, testing and study. Defendants failed to
13 perform adequate testing before exposing Plaintiff to the medication, testing which would have
14 shown that BEXTRA had the potential to cause serious side effects including the injuries suffered
15 like the Plaintiff.

16 83. BEXTRA as manufactured and supplied by Defendants was defective due
17 to inadequate post-marketing warnings or instructions because, after Defendants knew or should
18 have known of the risk of injuries from BEXTRA, they failed to provide adequate warnings to the
19 medical community and the consumers, to whom they were directly marketing and advertising
20 BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe and effective.

21 84. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised
22 and promoted defectively by Defendants, and as a direct and proximate cause of Defendants'
23 defective design of BEXTRA, Plaintiff used BEXTRA rather than other safer and cheaper
24 NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.

25 85. Information given by Defendants to the medical community and to the
26 consumers concerning the safety and efficacy of BEXTRA, especially the information contained
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1 in the advertising and promotional materials, did not accurately reflect the potential side effects of
2 BEXTRA.

3 86. Had adequate warnings and instructions been provided, Plaintiff would not
4 have taken BEXTRA, and would not have been at risk of the harmful side effects described
5 herein.

6 87. Defendants acted with conscious and deliberate disregard of the
7 foreseeable harm caused by BEXTRA.

8 88. Plaintiff could not, through the exercise of reasonable care, have
9 discovered BEXTRA's defects or perceived the dangers posed by the drug.

10 89. As a direct and proximate consequence of Defendants' acts, omissions, and
11 misrepresentations described herein, the Plaintiff sustained serious cardiovascular injuries; has
12 required and will require healthcare and services; has incurred and will continue to incur medical
13 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
14 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
15 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
16 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
17 direct medical losses and costs include care for hospitalization, physician care, monitoring,
18 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

19 90. Defendants' conduct was committed with knowing, conscious, wanton,
20 willful, and deliberate disregard for the value of human life and the rights and safety of
21 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
22 as to punish Defendants and deter them from similar conduct in the future.

23 91. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
24 compensatory damages, and punitive and exemplary damages together with interest, the costs of
25 suit and attorneys' fees and such other and further relief as this Court deems just and proper.
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THIRD CLAIM FOR RELIEF
Breach of Express Warranty

92. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

93. Defendants expressly represented to Plaintiff and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

94. These warranties came in the form of:

(a) Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;

(b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;

(c) Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;

(d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiff's ingestion of BEXTRA, and;

(e) advertisements.

95. The documents referred to above were created by and at the direction of Defendants.

96. Defendants knew or had reason to know that BEXTRA did not conform to these express representations in that BEXTRA is neither as safe nor as effective as represented, and that BEXTRA produces serious adverse side effects.

1 97. BEXTRA did not and does not conform to Defendants' express
2 representations because it is not safe, has numerous and serious side effects, including unwarned-
3 of side effects, and causes severe and permanent injuries.

4 98. Plaintiff, other consumers, and the medical community relied upon
5 Defendants' express warranties.

6 99. As a direct and proximate consequence of Defendants' acts, omissions, and
7 misrepresentations described herein, the Plaintiff sustained serious cardiovascular injuries; has
8 required and will require healthcare and services; has incurred and will continue to incur medical
9 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
10 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
11 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
12 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
13 direct medical losses and costs include care for hospitalization, physician care, monitoring,
14 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

15 100. Defendants' conduct was committed with knowing, conscious, wanton,
16 willful, and deliberate disregard for the value of human life and the rights and safety of
17 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
18 as to punish Defendants and deter them from similar conduct in the future.

19 101. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
20 compensatory damages, and punitive and exemplary damages together with interest, the costs of
21 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

22 **FOURTH CLAIM FOR RELIEF**
23 **Breach of Implied Warranty**

24 102. Plaintiff incorporates by reference all of the paragraphs of this Complaint
25 as if fully set forth herein.

26 103. Defendants manufactured, distributed, advertised, promoted, and sold
27 BEXTRA.
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1 104. At all relevant times, Defendants knew of the use for which BEXTRA was
2 intended and impliedly warranted the product to be of merchantable quality and safe and fit for
3 such use.

4 105. BEXTRA was not of merchantable quality and was not fit for its intended
5 use, because it causes increased risk of serious cardiovascular and cerebrovasclar adverse events,
6 including heart attacks, strokes and other serious and harmful adverse health effects.

7 106. Defendants breached the implied warranty that BEXTRA was of
8 merchantable quality and fit for such use.

9 107. Defendants were aware that consumers, including Plaintiff, would use
10 BEXTRA for treatment of pain and inflammation and for other purposes.

11 108. Plaintiff and the medical community reasonably relied upon Defendants'
12 judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was
13 indeed of merchantable quality and safe and fit for its intended use. Consumers, including
14 Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for
15 BEXTRA.

16 109. BEXTRA reached consumers, including Plaintiff, without substantial
17 change in the condition in which it was manufactured and sold by Defendants.

18 110. Defendants breached their implied warranty to consumers, including
19 Plaintiff; BEXTRA was not of merchantable quality or safe and fit for its intended use.

20 111. As a direct and proximate consequence of Defendants' acts, omissions, and
21 misrepresentations described herein, the Plaintiff sustained serious cardiovascular injuries; has
22 required and will require healthcare and services; has incurred and will continue to incur medical
23 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
24 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
25 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
26 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
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1 direct medical losses and costs include care for hospitalization, physician care, monitoring,
2 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

3 112. Defendants' conduct was committed with knowing, conscious, wanton,
4 willful, and deliberate disregard for the value of human life and the rights and safety of
5 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
6 as to punish Defendants and deter them from similar conduct in the future.

7 113. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
8 compensatory damages and punitive and exemplary damages together with interest, the costs of
9 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

10 **FIFTH CLAIM FOR RELIEF:**
11 **Fraudulent Misrepresentation & Concealment**

12 114. Plaintiff incorporates by reference all of the paragraphs of this Complaint
13 as if fully set forth herein.

14 115. Defendants' superior knowledge and expertise, their relationship of trust
15 and confidence with doctors and the public, their specific knowledge regarding the risks and
16 dangers of BEXTRA, and their intentional dissemination of promotional and marketing
17 information about BEXTRA for the purpose of maximizing its sales, each gave rise to the
18 affirmative duty to meaningfully disclose and provide all material information about BEXTRA's
19 risks and harms to doctors and consumers.

20 116. Defendants made fraudulent affirmative misrepresentations with respect to
21 BEXTRA in the following particulars:

22 (a) Defendants represented through their labeling, advertising,
23 marketing materials, detail persons, seminar presentations, publications, notice letters, and
24 regulatory submissions that BEXTRA had been tested and found to be safe and effective for the
25 treatment of pain and inflammation; and

26 (b) Defendants represented that BEXTRA was safer than other
27 alternative medications.
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1 117. Defendants made affirmative misrepresentations; and fraudulently,
2 intentionally and/or recklessly concealed material adverse information regarding the safety and
3 effectiveness of BEXTRA.

4 118. Defendants made these misrepresentations and actively concealed adverse
5 information at a time when Defendants knew or had reason to know that BEXTRA had defects
6 and was unreasonably dangerous and was not what Defendants had represented to the medical
7 community, the FDA and the consuming public, including Plaintiff.

8 119. Defendants omitted, suppressed and/or concealed material facts concerning
9 the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to,
10 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'
11 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the
12 serious nature of the risks associated with the use of BEXTRA in order to increase its sales.

13 120. The representations and concealment were undertaken by Defendants with
14 an intent that doctors and patients, including Plaintiff, rely upon them.

15 121. Defendants' representations and concealments were undertaken with the
16 intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to
17 induce and encourage the sale of BEXTRA.

18 122. Defendants' fraudulent representations evinced their callous, reckless,
19 willful, and depraved indifference to the health, safety, and welfare of consumers, including
20 Plaintiff.

21 123. Plaintiff's physicians and Plaintiff relied on and were induced by
22 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of
23 BEXTRA in selecting BEXTRA treatment.

24 124. Plaintiff and the treating medical community did not know that the
25 representations were false and were justified in relying upon Defendants' representations.
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1 125. Had Plaintiff been aware of the increased risk of side effects associated
2 with BEXTRA and the relative efficacy of BEXTRA compared with other readily available
3 medications, Plaintiff would not have taken BEXTRA as she did.

4 126. As a direct and proximate consequence of Defendants' acts, omissions, and
5 misrepresentations described herein, the Plaintiff sustained serious cardiovascular injuries; has
6 required and will require healthcare and services; has incurred and will continue to incur medical
7 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
8 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
9 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
10 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
11 direct medical losses and costs include care for hospitalization, physician care, monitoring,
12 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

13 127. Defendants' conduct was committed with knowing, conscious, wanton,
14 willful, and deliberate disregard for the value of human life and the rights and safety of
15 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
16 as to punish Defendants and deter them from similar conduct in the future.

17 128. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
18 compensatory damages, and punitive and exemplary damages together with interest, the costs of
19 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

20 **SIXTH CLAIM FOR RELIEF**
21 **(Unjust Enrichment)**

22 129. Plaintiff incorporates by reference all previous paragraphs of this
23 Complaint as if fully set forth herein.

24 130. At all times relevant to this action, Defendants were the manufacturers,
25 sellers, and/or suppliers of BEXTRA.

26 131. Plaintiff paid for BEXTRA for the purpose of managing her pain safely
27 and effectively.
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132. Defendants have accepted payment from Plaintiff for the purchase of BEXTRA.

133. Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.

134. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented BEXTRA to be.

135. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damage;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
8. Such other and further relief as the Court deems just and proper.

1 Dated: November 5, 2007

2 Respectfully submitted,

3
4 By: Navan Ward Jr.

5 Andy D. Birchfield, Jr. (BIR006)
6 Navan Ward, Jr. (WAR062)
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ATTORNEYS FOR PLAINTIFF

1 Dated: November 5, 2007

2 Respectfully submitted,

3
4 By: Navan Ward, Jr.

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ATTORNEYS FOR PLAINTIFF